News and Views From the Literature

Female Urology: Training and Regulations

Female Pelvic Medicine Fellowships—The Urogynecologist's Perspective

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Attitudes and Perceptions Regarding Subspecialty Training in Female Pelvic Medicine and Reconstructive Surgery

Siddighi S, Barker M, Pancholy A, et al.
Int Urogynecol J. 2008;19:1523-1526.

The field of female pelvic medicine and reconstructive surgery (FPMRS) is a relatively new subspecialty in the fields of urology and obstetrics/gynecology (ob-gyn). Physicians who choose to specialize in this rapidly growing area of medicine develop an expertise in areas of gynecology, female urology, and colorectal surgery, and also study disorders of the pelvic floor and viscera.

Based on the current result of the National Resident Matching Program, fewer US senior medical students are specializing in ob-gyn. The most commonly cited reasons are issues with professional liability and the impact of long hours on quality of life.

The objective of the study was to evaluate perceptions regarding subspecialty training in FPMRS in the United States. A 57-item questionnaire was anonymously mailed to fellows and applicants to FPMRS fellowship. Seventy-four American fellowship interviewees and current fellows completed the entire questionnaire (56% response rate). Key factors associated with higher interest in FPMRS compared with general ob-gyn included competitiveness of the fellowship and new developments in the field. Key factors associated with higher interest in FPMRS compared with other subspecialties in ob-gyn were lower risk of malpractice and a higher sense of career satisfaction.

The majority of responders preferred academics over private practice or a mixture (55.4%, 17.6%, and 27%, respectively). The most important reasons for interest in FPMRS are quality time in the operating room and lower risk of malpractice. Additional attractive features include complexity of cases and the quantity of time spent in the operating room.

This study attempted to look at why FPMRS is so popular and attracting the best of the ob-gyn residents. This study showed that risk of malpractice, impact on personal time, and level of stress were believed to be low in FPMRS. Career satisfaction was found to be lower in ob-gyn than

either general surgery or primary care. This study found that there is a higher sense of career satisfaction among fellows and faculty in FPMRS than in general ob-gyn.

FDA Public Health Notification: Serious Complications Associated With Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence

Schultz DG.

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm061976.htm

Following is the text of a US Food and Drug Administration Public Health Notification that was issued on October 20, 2008.

> This is to alert you to complications associated with transvaginal placement of surgical mesh to treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI). Although rare, these complications can have serious consequences. Following is information regarding the adverse events that have been reported to the FDA and recommendations to reduce the risks.
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> **Nature of the Problem**
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> Over the past 3 years, FDA has received over 1,000 reports from 9 surgical mesh manufacturers of complications that were associated with surgical mesh devices used to repair POP and SUI. These mesh devices are usually placed transvaginally utilizing tools for minimally invasive placement.
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> The most frequent complications included erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence. There were also reports of bowel, bladder, and blood vessel perforation during insertion. In some cases, vaginal scarring and mesh erosion led to a significant decrease in patient quality of life due to discomfort and pain, including dyspareunia.
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> Treatment of the various types of complications included additional surgical procedures (some of them to remove the mesh), IV therapy, blood transfusions, and drainage of hematomas or abscesses.
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> Specific characteristics of patients at increased risk for complications have not been determined. Contributing factors may include the overall health of the patient, the mesh material, the size and shape of the mesh, the surgical technique used, concomitant procedures undertaken (eg hysterectomy), and possibly estrogen status.
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> **Recommendations**
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> Physicians should:
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> - Obtain specialized training for each mesh placement technique, and be aware of its risks.
> - Be vigilant for potential adverse events from the mesh, especially erosion and infection.
> - Watch for complications associated with the tools used in transvaginal placement, especially bowel, bladder and blood vessel perforations.
> - Inform patients that implantation of surgical mesh is permanent, and that some complications associated with the implanted mesh may require additional surgery that may or may not correct the complication.
> - Inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring, and narrowing of the vaginal wall (in POP repair).
> - Provide patients with a written copy of the patient labeling from the surgical mesh manufacturer, if available.
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> Additional patient information can be found on the following FDA Consumer website at http://www.fda.gov/cdrh/consumer/surgicalmesh-popsui.html.
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> **Reporting Adverse Events to FDA**
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> FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of surgical mesh, you should follow the reporting procedure established by your facility.
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> We also encourage you to report adverse events related to surgical mesh that do not meet the requirements for mandatory reporting. You can report directly to MedWatch, the FDA Safety Information and Adverse Event Reporting program online at www.fda.gov/MedWatch/report.htm, by phone at 1-800-FDA-1088, or obtain the fillable form online at www.fda.gov/MedWatch/getforms.htm, print it out and fax to 1-800-FDA-0178 or mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787.

With my personal interest (MBC) in stem cell and tissue engineering and previous investigation of biologic sling materials in the animal model, I have always believed that the future of pelvic floor reconstruction was the use of biologic slings and patches to regenerate the pelvic floor and deficient sphincter. Over the past decade, I have used autologous fascia, cadaveric fascia, and biologically based material using small intestine submucosa (SIS; Surgisis® Biodesign™, Cook Medical, Bloomington, IN) with efficacy and avoidance of synthetic material complications. Made from purified pig intestine, SIS has been shown to have growth factors that signal surrounding tissue to grow across the sling and to help the body to repair itself. Perhaps new biologic surgical graft material can lead to the development of an entirely new category of tissue repair and wound management options.

The currently accepted, loosely woven, monofilament type I polypropylene meshes appear to have acceptable

lower exposure rates in the range of 1% to 3% for slings, but with the larger area of mesh used in prolapse repairs, the rate increases to up to 10%. With the current widespread use of graft materials to reinforce pelvic floor reconstructive techniques, it is imperative for surgeons to be familiar with potential complications related to the materials and proper management of these complications. Although it appears that the benefit of using some synthetic materials may outweigh the risks, proper management and understanding of the risks is important to counsel our patients appropriately and responsibly prior to surgery. ■

Prostate Cancer

Randomized Trials of Prostate Cancer Screening

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Since the introduction of widespread prostate-specific antigen (PSA)–based prostate cancer screening, there has been a considerable stage migration.[1] Prior studies have shown that PSA screening reduces the risk of advanced disease compared with no screening,[2,3] but there were insufficient data to prove that screening saves lives. Until recently, randomized trials demonstrating Level I evidence have not been available to determine whether prostate cancer screening leads to a mortality benefit. In March 2009, the European Randomized Study of Screening for Prostate Cancer (ERSPC) and Prostate, Lung, Colorectal, and Ovarian (PLCO) trials reported on mortality results.

Screening and Prostate-Cancer Mortality in a Randomized European Study

Schröder FH, Hugosson J, Roobol MJ, et al.
N Engl J Med. 2009;360:1320-1328.

Schröder and colleagues reported on the mortality rates in 162,243 men aged 55 to 69 years from ERSPC. Men from 7 European countries were identified through population registries and randomized into screening and control arms. It is noteworthy that PSA screening was uncommon in Europe at the time this trial was initiated, such that this represented a population with relatively low levels of prescreening. Most centers performed screening at 4-year intervals and used a serum PSA level of 3 ng/mL as the threshold for biopsy, although digital rectal examination (DRE) was primarily used as an ancillary test for men with PSA levels greater than 3 ng/mL.

The mean age was 60.8 years at randomization and men in the screening arm received an average of 2.1 PSA tests per person. The cumulative incidence of prostate cancer was 8.2% in the screening arm and 4.8% in the control arm. Thus, screening compared with no screening led to an expected increase in prostate cancer incidence.

At a median follow-up of approximately 9 years, prostate cancer death occurred in 214 men from the screening arm versus 326 controls (adjusted rate ratio 0.80; 95% confidence interval [CI], 0.65-0.98; $P = .04$) in the intent-to-screen analysis. A separate analysis of men who actually underwent screening in the first round (82% compliance) to those who did not demonstrated a 27% reduction in prostate cancer mortality. Of note, the difference in mortality emerged after 7 to 8 years, and appeared to increase over time. In addition to the reduction in mortality, the screening arm had a 41% lower rate of metastases at the time of diagnosis than the control arm.

Despite the favorable mortality results, Schröder and colleagues also highlighted the potential harms of screening with respect to overdiagnosis. The prostate cancer incidence rate was 70% higher in the screening arm than the control arm. As a comparison, a systematic review of breast cancer screening similarly demonstrated a 15% to 20% relative reduction in cancer-specific mortality with mammography, with only a 30% increase in incidence.[4]

Overall, Schröder and colleagues estimated that 1410 men would need to be screened and an additional 48 men treated to prevent 1 prostate cancer death over 9 years. However, the number needed to treat to prevent 1 case of metastatic prostate cancer was approximately 25 compared with the ERSPC control group (F. H. Schröder, MD, personal communication, 2009), and only 15 compared with a population from Northern Ireland with virtually no screening.[5]

Mortality Results From a Randomized Prostate-Cancer Screening Trial

Andriole GL, Crawford ED, Grubb RL 3rd, et al.
N Engl J Med. 2009;360:1310-1319.

The Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial was designed by the National Cancer